K091645

JUL 21 2009

3. 510(k) Notification Cover Letter

FDA CDRH DMC
JUN 04 2009
Received

3.1. Administrative Information

Type: Traditional 510(k) submission

Device type: accelerator, linear, medical

510(k) submitter: Naslund Medical AB

Contact persons: Tomas Naslund

No confidentiality needed concerning the existence of this premarket notification

Regulation Number: 892.5050

Class: 2

Review Panel: 90 (Radiology)

Product Code: IYE

No prior correspondence exists related to this device

Establishment Regestration nr: Will register following FDA clerance

3.2. Design and Use of the Device

Is the device intended for prescription use?	Yes
Is the device intended for over-the-counter use?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	Yes
Is the device intended for single use?	Yes
Is the device a reprocessed single use device?	No
If yes, does this device type require reprocessed validation data?	N/A
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	No
Does the submission include clinical information?	No
Is the device implanted?	Yes

3.3. 510(K): Comparison with a predicate device

	Manufacturer	Device	510(k) #
New	Naslund Medical AB	Gold Anchor	Not applicable
Cleared	Radiomed Corporation	Preloaded Radi-oMed Soft Tissue Marker	K070305

7. Device Information

7.1. Description of New Device Gold Anchor

The Gold Anchor Marker consists of a thin gold wire with cutouts delivered in a fine needle.The Gold Anchor Marker is available pre-loaded in two different sizes of fine needles: Gold Anchor 120 comes in a 0.53 mm x 120 mm (25 G x 4 3/4") fine needle with an attached injector, and Gold Anchor 200 comes in a 0.7mm x 203mm (22G x 8") fine needle.

The Gold Anchor comes in blister single packs, sterilized, ready for use, in lengths of 1-5cm, clearly indicated on the package. They shall be implanted under guidance of ultra-sound or CT or during manual palpation of the tumor.

The Gold Anchor Marker can be inserted in the tissue in two ways, either through advancing the stylet or by withdrawing the needle. If the stylet is advanced rather than the needle withdrawn, the Gold Anchor Marker will collapse and fold into different shapes. By withdrawing the needle the Gold Anchor Marker will be deposited as a straight line in the needle track.

(ref 1.1) Gold Anchor GA120 product overview

(ref 2.2) Gold Anchor GA200 product overview

7.2. Intended Use of Gold Anchor

The Gold Anchor Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

7.3. User Characteristics

Gold Anchor is intended to be used by qualified medical staff trained in using fine needle operations, e.g. radiologist, radiotherapist, cytologist or equivalent.

8. Substantial Equivalence Discussion

8.1. Comparison to Predicate Devices

Device	Name	510(k) #
New	Gold Anchor	Not applicable
Cleared	Preloaded RadioMed Soft Tissue Marker *	K070305

*Aslo known as Visicoil

8.2. Indications for Use, Intended Use

The Intended Use of the new device is shown below.

Device	Intended Use
Cleared	The Preloaded RadioMed Soft Tissue Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.
New	The Gold Anchor Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

8.3. Comments on the Preloaded RadioMed Soft Tissue Marker predicate Device

The Preloaded RadioMed Soft Tissue Marker is a sterile device, in the form of a gold coil loaded into a 17, 18 or 19g needle. The coil ranges in OD between 0.35mm and 1.1 mm. Depending on the coil size (0.35mm, 0.75mm, or 1.10mm), the Pre-Loaded Visicoil Marker will be delivered using either a 17, 18 or 19 gauge needle. The coil is supplied loaded and ready for use in the applicable needle. It is sterilized using EO.

8.4. Predicate Device technical characteristics - Preloaded RadioMed Soft Tissue Marker

The predicate device is made out of pure gold. It is delivered sterile, for single use, preloaded and preplugged in 17, 18, 19 gauge needles. The markers range from 0.35-1.1 mm in diameter and 10-60 mm in length. It is Sterililized using EO.

8.5. Scientific technology - Preloaded RadioMed Soft Tissue Marker

The Scientific Technology of the new device is essentially the same as the Scientific Technology for the cleared device, the Preloaded RadioMed Soft Tissue Marker, as shown below. The following table demonstrates that the modified device has the same technological characteristics and is similar in design, function, and application to the predicate device.

Item	Statement of Equivalence or Difference compared to Predicate device
Indications for Use	Same as predicate device
Target Population	Same as predicate device
Design	Same as predicate device
Materials	Same as predicate device
Performance	Same as predicate device
Sterility	Different - Electronic Beam Radiation
Biocompatibility	Same as predicate device
Mechanical Safety	Same as predicate device
Chemical Safety	Same as predicate device
Anatomical Sites	Same as predicate device
Human Factors	Same as predicate device
Energy Used and/or Delivered	Same as predicate device

Item	Statement of Equivalence or Difference compared to Predicate device
Compatibility with Environment and Other Devices	Same as predicate device
Where Used (Hospital)	Same as predicate device
Standards	Same as predicate device
Electrical Safety	Same as predicate device
Thermal Safety	Same as predicate device
Radiation Safety	Same as predicate device
Prescription use only	Same as predicate device

8.6. Technical Characteristics: Detailed Comparison with Predicate Devices

The new device is in conformance with the recognized and international standards, which cover the Safety and Effectiveness of the modified device as discussed in chapter 14.

The similarity and differences between the modified device and the legally marketed predicate device are listed below:

Technical Characteristics	*Cleared* Pre-Loaded RadioMed Soft Tissue Marker K070305	*New* Gold Anchor	Change in scientific technology	Changes in Intended use
Dimensions				
Material	Pure metallic gold 99.95%	Pure metallic gold Minimum 99.95%	No	No
Length of marker	10-60mm	10-50mm	No	No
Intended use	The Preloaded RadioMed Soft Tissue Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.	identical	No	No
Preloaded in needle	yes	yes	No	No
Preplugged/vaxed needle	yes	yes	No	No
Other				
Operating areas	Hospital	Same	No	No
Operated by	Physician	Same	No	No
Standards met	FDA QSR 2 1 CFR Part 820 Good Manufacturing Practices	Same	No	No
Differences				
Needle size	17,18,19 g	22,25 g	No	No
Diameter of marker	0,35-1,10 mm	0,28 mm	No	No
Sterility	EO	Electronic Beam Radiation	Yes	No

8.7. Summary of Technological Characteristics and Intended Use

The intended use for this new device is identical to that of its predicate device.

The Gold Anchor is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

The fundamental scientific technology of the modified device has not changed.

- The material used for both the predicate device and the new device is pure metallic gold.
- The intended use for both the predicate device and the new device are identical.

- Both the predicate device and the new device are delivered sterile in pre-plugged/vaxed introducer needles.

The change to this product includes the following:

- Predicate device exist in the form of a coil. The new device exists in a form of thin wire with cut-outs.
- Predicate device uses 17, 18, 19 gauge needles while the new device uses 22, 25 gauge needles.
- Predicate device uses EO sterilization while the new device uses Electron Beam Radiation.

These differences do not add any new hazards to the Gold Anchor system compared with the Predicate device and thus Gold Anchor is substantially similar to the Predicate Device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2009

Mr. Tomas Naslund
Product Manager
Naslund Medical AB
Vassvagen 21, Huddinge, 14139
SWEDEN

Re: K091645
Trade/Device Name: Gold Anchor
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 1, 2009
Received: June 4, 2009

Dear Mr. Naslund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K091645

Device Name Gold Anchor.

Indications for Use Gold Anchor is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091645